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(b) Address the implementation of, and results from, the quality assessment and performance improvement plan.

(c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

§ 460.140 Additional quality assessment activities.

A PACE organization must meet external quality assessment and reporting requirements, as specified by HCFA or the State administering agency, in accordance with § 460.202.

Subpart I—Participant Enrollment and Disenrollment

§ 460.150 Eligibility to enroll in a PACE program.

- (a) General rule. To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in §460.160.
- (b) Basic eligibility requirements. To be eligible to enroll in PACE, an individual must meet the following requirements:

(1) Be 55 years of age or older.

(2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(3) Reside in the service area of the PACE organization.

- (4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These additional conditions may not modify the requirements of paragraph (b)(1) through (b)(3) of this section.
- (c) Other eligibility requirements. (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.
- (2) The criteria used to determine if an individual's health or safety would be jeopardized by living in a commu-

nity setting must be specified in the program agreement.

- (d) Eligibility under Medicare and Medicaid. Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:
 - (1) Entitled to Medicare Part A.
 - (2) Enrolled under Medicare Part B.
 - (3) Eligible for Medicaid.

§ 460.152 Enrollment process.

- (a) Intake process. Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:
- (1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:
- (i) The PACE program, using a copy of the enrollment agreement described in §460.154, specifically references the elements of the agreement including but not limited to §460.154(e), (i) through (m), and (r).
- (ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.
- (iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under §460.70(c).
 - (iv) Monthly premiums, if any.
- (v) Any Medicaid spenddown obligations.
- (2) The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.
- (3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required

under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligi-

bility specified in this part.

- (b) Denial of Enrollment. If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must meet the following requirements:
- (1) Notify the individual in writing of the reason for the denial.
- (2) Refer the individual to alternative services, as appropriate.
- (3) Maintain supporting documentation of the reason for the denial.
- (4) Notify HCFA and the State administering agency and make the documentation available for review.

§ 460.154 Enrollment agreement.

If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

- (a) Applicant's name, sex, and date of
- (b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.
- (c) Medicaid recipient status and number, if applicable.
- (d) Other health insurance information, if applicable.
- (e) Conditions for enrollment and disenrollment in PACE.
- (f) Description of participant premiums, if any, and procedures for payment of premiums.
- (g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under §460.184.

(h) Notification that a Medicare participant may not disenroll from PACE at a social security office.

- (i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE.
- (j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.
- (k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.
- (I) Description of the procedures for obtaining emergency and urgently needed out-of-network services.
 - (m) The participant bill of rights.
- (n) Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals.
- (o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.
- (p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.
- (q) A statement that the PACE organization has an agreement with HCFA and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated.
- (r) The applicant's authorization for disclosure and exchange of personal information between HCFA, its agents, the State administering agency, and the PACE organization.
 - (s) The effective date of enrollment.
- (t) The applicant's signature and the date.

§ 460.156 Other enrollment procedures.

(a) Items a PACE organization must give a participant upon enrollment. After the participant signs the enrollment agreement, the PACE organization